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Respiratory protective devices — Human factors —

Part 8: Ergonomic factors

Appareils de protection respiratoire — Facteurs humains —

Partie 8: Facteurs ergonomiques

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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The committee responsible for this document is ISO/TC 94, *Personal safety — Protective clothing and equipment*, SC15, *Respiratory protective devices*.

ISO/TS 16976 consists of the following parts:

— *Part 1: Metabolic rates and respiratory flow rates*

— *Part 2: Anthropometrics*

— *Part 3: Physiological responses and limitations of oxygen and limitations of carbon dioxide in the breathing environment*

— *Part 4: Work of breathing and breathing resistance: Physiologically based limits*

The following parts are under preparation:

— *Part 5: Thermal effects*

— *Part 6: Psycho-physiological effects*

— *Part 7: Hearing and speech*

Introduction

This part of ISO/TS 16976 provides guidance for the writers of respiratory protective devices (RPD) performance standards on the specification of ergonomic factors.

Ergonomics involves the application of scientific methods and appropriate data to the design and specification of machines, equipment, environments, systems and the interface with the people using it. The successful use of ergonomics in designing RPD will enhance the acceptability of the RPD and through this will improve the safety, health, performance and effectiveness of the wearer.

RPD is used in situations where a risk to health or safety has been identified. The preferred solution is to reduce the risk to zero and thereby to remove the need for RPD. If this is not possible, the threat should be reduced so that practical RPD can minimize the risk to wearer exposed to that hazard. In some working conditions some RPD may be more comfortable than none and not to be considered as an additional discomfort. Side effects of using RPD can range from discomfort to severe constraint and physical load. The application of ergonomic principles to RPD allows optimization of the balance between protection and usability.

Some aspects of the design and specification of RPD require specialist knowledge of the particular job the RPD is used for and of the particular hazard against which the RPD is to be effective or particular ergonomics issues. Although this part of ISO/TS 16976 covers many aspects, the writers of performance standards should be aware that it cannot be expected to identify all the existing and possible future problem points for which ergonomic factors and test methods will be required in performance standards. It will remain the responsibility of the relevant experts to identify and quantify the hazards in the work place and to foresee the potential ergonomic problems, and thus to ensure that the RPD specified and manufactured is fit for the purposes intended in all respects.

For practical reasons, this part of ISO/TS 16976 presents ergonomics factors separately. However, it should be recognized that the overall acceptability of a RPD will be determined by a combination of these and other factors by the individual wearer.

Together with ISO/TS 16976 Parts 1 to 7, this part of ISO/TS 16976 provides basic human factor data.

Respiratory protective devices — Human factors —

Part 8: Ergonomic factors

1 Scope

ISO/TS 16976 provides information on factors related to human physiology, ergonomics and performance for the preparation of standards for performance requirements, testing and use of respiratory protective devices (RPD).

This part of ISO/TS 16976 gives guidance on the generic ergonomic factors related to RPD.

It specifies for the writers of RPD performance standards principles relating to:

— the biomechanical interaction between RPD and the human body;

— the interaction between RPD and the human senses: vision, hearing, smell, taste and skin contact.

This part of ISO/TS 16976 does not cover requirements related to specific hazards for which RPD are designed.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 16972, *Respiratory protective devices — Terms, definitions, graphical symbols and units of measurement*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 16972 apply.

4 Ergonomic factors

4.1 General

Harmonized performance standards for RPD should contain ergonomic requirements and test methods, or should make normative reference to other standards to be applied.

Usually, ergonomic assessments of RPD have to be made while people are wearing them or are connected to the external component of the system. Wherever possible, the assessments should be objective, although some aspects can only be assessed subjectively.

Examples of how to make assessments are given in Annex A.

4.2 Integration of performance and ergonomic requirements

The primary purpose of RPD is to provide protection against specific inhalation hazards that cannot be eliminated or adequately reduced by other means. Performance standards should therefore contain performance requirements and test methods to ensure that the products fulfilling the performance

provide the appropriate protection against the identified hazards, and that they are ergonomically suitable for the users.

Performance standards writers should consider the tasks being performed, the equipment being used, the duration of the usage of the RPD, and the environments likely to be encountered. They should ensure as far as possible that the RPD does not create hazards for the users. This may be by incorporating in performance standards requirements and test methods based on this part of ISO/TS 16976.

Where the presence of more than one risk or the need to cover more parts of the body makes it necessary for a wearer to use simultaneously besides an RPD another item of Personal Protective Equipment (PPE), such equipment must be mutually compatible and continue to be effective against the risk or risks in question.

In addition to interactive effects on technical performance, interaction between different forms of PPE including RPD may influence ergonomic aspects. Thus, although the effect of individual items of PPE tested in isolation may not be significant, it will be the combined effect that will determine the overall load and consequent acceptability. For example, both a half-mask respirator and a safety helmet may intrude upon the visual field (glasses). Either in isolation may be acceptable but, when worn together the combined impact may not be. At its most extreme, extensive body coverage by RPD, or wearing several forms of protection may result in sensory and physical isolation.

Ergonomics requirements can be taken into account by determination of performance levels on the basis of a risk assessment.

4.3 Factors to be considered in the determination of the best ergonomic solution

4.3.1 General

RPD is to be worn by an individual for protection against one or more health and safety hazards. This protection is the intended effect of the RPD, but wearing RPD can also result in unintended negative effects, which can interfere with the wearer's normal performance of the risk-related tasks.

Performance standards writers should consider how to specify the best compromises between protection, practicality, and any potentially adverse impact of wearing the RPD. If different solutions apply, equivalent compromises may be possible.

4.3.2 Factors to be considered in specifying the optimum level of protection to be provided

Performance standards writers should consider the following variable aspects of the use of RPD:

— the duration of use of the RPD (some RPD such as escape RPD may be worn for only a few minutes when it is perceived that a hazard is present, but other RPD may be worn for several hours or throughout a working day/shift);

— whether there are different situations in which the RPD is used, that require different amounts of the body to be covered and for various other PPE to be used in addition;

— the reasonable balance between the severity of the hazard, protection, burden and duration.

4.3.3 Factors to be considered in specifying the optimal practicability

The designs of RPD that result from compliance with performance standards should allow, as far as possible, normal pursuit of all activity within the occupational environment. To ensure this is achieved, performance standards should include test procedures and requirements based on the performance of prescribed movements, or should make normative reference to such procedures and requirements. Standards writers should, where relevant, include reference to the fact that where RPD suppliers claim mutually compatible components of PPE, the resulting combination should be tested together. Tests should be selected to represent a range of the normal movements made by wearers of the RPD while using it.

For fire fighter PPE assessment, standard writers should refer to BS 8469.[19]

In any event they should include the following:

— understanding instructions and warnings given by the manufacturers;

— putting on, adjusting, and taking off the RPD and/or PPE;

— general activities, such as moving and communicating;

— activities specific to situations where the RPD is to be used;

— safety of the subjects.

Practical performance tests may impose physiological strains on the test subjects thus requiring stringent controls. To ensure the safety of test subjects:

a) the test subjects should be medically examined and certified fit in accordance with ISO 12894[5];

b) ethical clearance should be obtained in accordance with Reference;[20]

c) the experimentation should be performed in accordance with Reference;[20]

d) there should be physiological monitoring of test subjects;

e) normal safety procedures should be applied, including close supervision by trained, experienced staff, and voluntary withdrawal should be permitted at any time.

Interpretation of the results should take into account the levels of hazard against which the RPD is intended to provide protection, the inevitable burdens such RPD will impose, and the environmental conditions under which it will be used.

Guidance on the choice of movements and the overall conduct of ergonomic assessment of RPD using human subjects is given in Annex A.

For more information, see ISO/TS 16976-1[9], ISO/TS 16976-3[11] and ISO/TS 16976-5[12].

4.3.4 Factors to be considered in the physiological impact of RPD

The following indicators might be considered to determine the physiological impact in relation to the use of RPD:

— heart rate,

— oxygen consumption,

— alveolar gas composition,

— breathing rate,

— body temperature change,

— sweat rate,

— fatigue or strain of muscles.

Examples where indicators might be used include where the mass of the RPD may result in an excessive burden or where the exothermic processes providing breathable air or other factors of RPD may give rise to thermal strain.

More information may be obtained in ISO/TS 16976-1[9] and ISO/TS 16976-3[11].

4.4 Factors to be considered in specifying requirements for the adjustability of RPD and its appropriate fixation to the body

Performance standards writers should consider whether requirements and test methods need to be included to test the adjustments and restraint of RPD. In deciding that need, they should consider the seriousness of the consequences of displacement of the RPD, and the maximum tolerable displacement. The following are examples of aspects that could be considered:

— the information and instructions for fitting and adjusting;

— the information and instructinos for doffing of the RPD;

— the adjustability and the stability of adjustments;

— determining that the RPD has been correctly fitted.

When writing a test, consideration should be given to the static and dynamic forces that might be exerted on the RPD in normal wear, and during the circumstances in which it is intended to provide protection and how these may be represented in test methods.

4.5 Factors to be considered in specifying requirements to ensure that RPD does not irritate or cause discomfort

RPD shall not irritate or cause discomfort which may later lead to injuries for the users who may come into contact with it. Factors to be taken into account include:

— whether the RPD will be in contact with the skin and how sensitive this particular area of skin is to the effects of rubbing and pressure;

— for how long the RPD will normally be in contact with the skin;

— whether the type of RPD may have sharp or hard edges or points;

— whether the bulk, hardness and position of adjustment and closure mechanisms may have a negative impact on the user;

— whether chemical composition of the material used and its by-products may affect the body;

— whether any materials likely to be used in contact with the skin are known to produce allergic reactions in a proportion of the population;

— whether any closure mechanism, or other feature, may become caught up with scalp, facial or body hair;

— whether the outer surface of the RPD could harm other people;

— whether simple visual and manual examination of the RPD is adequate for an assessment, or whether specific test methods need to be developed for assessing the hardness, roughness or other features of the RPD.

4.6 Factors to be considered in specifying requirements to take into account the anthropometric factors of RPD

In determining appropriate anthropometric factors of the intended RPD wearer group to be specified in the RPD performance standards, the following shall be considered:

— the body part(s) it will be in contact with or cover;

— the physical activities expected to be performed during its use.

The body part(s) the RPD will be in contact with will serve to identify those parts for which anthropometric data are needed. If the RPD crosses or covers a body joint, then more anthropometric dimensions should be specified based on different joint positions.

The physical activity expected to be performed during the use of RPD may alter body dimensions. This should be taken into account in specifying anthropometric dimensions in a RPD performance standard. Excessively close fitting or otherwise poorly dimensioned RPD may prevent or hinder the performance of necessary activities.

Loose fitting or bulky RPD may restrict access to working areas or may present a potential safety hazard by snagging on projections or other features of the environment.

The intended user group will need to be defined to ensure that appropriate dimensions are specified to encompass that population. Variations in size may be accommodated by means of adequate adjustment systems or the provision of size ranges as appropriate.

Because different body dimensions are not necessarily closely correlated, standards writers should consider the need to specify more than one essential anthropometric dimension in order to ensure satisfactory fit for the intended user group.

Performance standards writers should address at least the topics related to anthropometric factors detailed in ISO/TS 16976-2[10] and in ISO 15537[6].

4.7 Factors to be considered in specifying requirements to take into account the biomechanical factors of RPD

4.7.1 General

In determining appropriate biomechanical effects to be specified in the RPD performance standards, the following should be considered:

- the static distribution of mass, the dynamic or inertial forces and consequent load on the human body when using different types of RPD and/or combinations of RPD and PPE,
- optimization of the influence of biomechanical effects of RPD on workload and/or task performance.

RPD can have adverse effects on the body by increasing muscle strain or energy consumption through increased passive loading or by altering the dynamic loading. For example, additional mass on the head produces forces in the neck that have to be countered by the neck muscles.

The mass of RPD and its distribution have to be considered in relation to the specific body part or parts likely to be affected.

Heavy masses on the body or body parts increase energy consumption, especially when walking or running.

Care should be taken when applying the principles in this section of this document to RPD intended to be worn under water or in situations involving unusual accelerative forces.

4.7.2 Mass distribution

Peripheral parts of the body are more susceptible to added mass than the trunk, because of the increased moment. Hence, an additional weight is best worn on the trunk and as close as possible to the body centre of gravity and as symmetrical as possible. This means that the waist is the body location where such a weight is best carried. However, this is often not practical because RPD is normally made to be worn on specific body parts in order to protect against a specific risk.

4.7.3 Restriction and prevention of movements

Heavy, close fitting, stiff or bulky material can excessively impede the bending of joints and restrict working positions and movements. Materials and products that resist movement elastically and require a continuous muscular effort acting against the elastic recoil to maintain a particular joint position can cause fatigue and injury.

4.7.4 Abrasion or compression of the skin and underlying structures

Movement of RPD against the body can give rise to redness (erythema) and, if prolonged, to abrasion. Depending upon the duration of wear, compression of the skin can cause unsightly marking. Where blood vessels or nerves pass close to the body surface or are liable to be trapped against hard (bony) body parts then further adverse effects can occur. For example, straps passing close to the neck/shoulder junction can compress nerves or occlude blood flow. Abrasion or compression might cause irritation or reduce the acceptability of the RPD. Pulse points in the neck, groin and wrist are obvious possible areas for concern in relation to circulatory effects.

4.7.5 Exacerbation of vibration

In some situations RPD, interacting with an external force, can produce vibration or shock effects. Some forms of RPD can impart additional vibration to the body of the wearer such as effects of vibration exposure, when wearing RPD during travelling in vehicles. The writers of performance standards should be aware of the special circumstances where such phenomena occur and, if appropriate, should include suitable testing within their standard.

4.8 Factors to be considered in specifying requirements to take into account the thermal effects of RPD

4.8.1 General

In the preparation of performance standards ergonomic factors should be considered so that the protective function of the RPD is maintained at the best possible level of thermal comfort for the wearer.

It is evident that RPD which does not put severe restrictions on heat exchange would considerably improve wearer comfort and efficiency. This can to some extent be achieved by appropriate material selection and designs.

Whenever possible, RPD shall be designed so that covered body parts can maintain good ventilation and moisture exchange when this is necessary. For example, the condensation of moisture from exhaled air occurs with many forms of RPD and this can result in local thermal discomfort.

The overall effect on the wearer’s heat exchange depends on the interaction between the thermal environment, activity, clothing and RPD. Therefore, RPD or combined RPD and workwear and/or other clothing have an upper and a lower range of environmental conditions for defined activity levels within which there will be little discomfort for the user. Proper specification of such limits, and/or thermal properties for the calculation of such limits should be given in performance standards.

4.8.2 Thermal effects of materials and complete RPD

Attention shall be paid to the selection of materials for RPD which shall not only provide the required protection against the relevant hazards, but should also interfere as little as possible with body heat balance. The aim is to obtain thermal comfort and minimize thermal strain.

The performance standard writer should bear in mind that the thermal effects of multi-layer materials or of RPD enclosing the whole body may not be the same as the sum of those of the individual materials.

The performance standard writer should bear in mind that the impact of the thermal effects of the complete RPD will be influenced by the thermal environment in which the RPD is to be worn and the physical activity of the wearer.

Performance standards writers should address thermal effects by considering the information given in ISO/TS 16976-5[12].

4.9 Factors to be considered in specifying requirements to take into account the sensory effects of RPD

4.9.1 General

The human senses are the means through which the human body receives information from the environment. Reception of the correct information is often a precondition for taking appropriate reactions. In a working situation the information can for example be about the environment, spoken information from other persons, visual information from papers, machinery or displays; feed-back from the working process; or warning signals. If the sensory signals are too weak or distorted there is a risk that they will either not be received or will be misunderstood. If the sensory signals are too strong or prolonged, the annoying effect can cause distraction, or symptoms such as fatigue and pain.

4.9.2 Vision

RPD might affect the wearer's vision adversely. Two possible examples, which are sometimes combined, are a decrease in the extent of the visual field and a reduction in optical transmission within the field of vision i.e. a reduction in the quantity or quality of visual information and the interpretation of warning signals. When designing respiratory interfaces that cover the eyes or are used in conjunction with goggles and spectacles, the impact on visual aspects should be taken into account. RPD should also be designed to allow wearers of corrective glasses to comply with the wearing of the RPD when obtaining the necessary visual correction and still achieve both protection and comfort.

4.9.3 Hearing and speech

RPD can hinder the receipt or transmission of auditory signals or information which the user either wants to hear (e.g. speech) or needs to hear (e.g. warning signals). For example, RPD may cover the ears (e.g. hooded type respiratory interface) or create disturbing noise or vibration.

Performance standards writers should address hearing and speech by considering the information given in ISO/TS 16976-7[13].

4.9.4 Odour or taste

Strong odours or tastes from the RPD might create a hazard to health by masking the odour or taste of a hazardous or toxic substance. Unpleasant odour or taste can also cause discomfort either when using the RPD or, if the odour persists afterwards, it may be given as a reason for not using RPD.

4.9.5 Touch or other skin contact

Wearing RPD can have undesirable sensory effects either by impeding the acquisition of information by the sense of touch, or by creating conflicting stimuli from contact with the RPD.

5 Verification procedure for compliance with ergonomic factors

5.1 General approach

5.1.1 In order to ensure that the standard being written includes appropriate provisions to ensure compliance of the RPD with the ergonomic requirements it is necessary to check that all ergonomic factors have been considered. To determine the relevance and importance of these different factors they should be considered within the context of:

- the reason for using the RPD (hazard);
- the conditions of use of the RPD including:
  - the intended wearer group,

- the tasks to be performed,
- the frequency and duration of the tasks,
- the environments in which the RPD is to be used.

5.1.2 Using the following list, which is not presented in any particular order, the standard writer should verify that the relevant ergonomics factors have been taken into consideration within the above context and, if appropriate, tests have been included in the standard.

- adequate fit due to adjustability and stability;
- intelligibility of instruction [does the deliverable allow the wearer to operate the RPD correctly (donning, doffing, adjusting, controls, operating....)];
- mass and mass distribution;
- essential dimensions;
- restriction and prevention of movements;
- irritation, abrasion or compression of the skin and underlying structures;
- exacerbation of vibration;
- thermal comfort;
- physiological impact;
- visual;
- auditory;
- odour or taste;
- touch or dexterity.

5.2 Selecting an appropriate type of test

A number of different types of tests (see Table 1) can be considered by RPD standards writers in writing clauses relating to verifying that an item of RPD complies with appropriate ergonomic factors. The selection and specification of an appropriate procedure will be determined by reference to the potential consequences of inadequate compliance. Whichever type of test is specified, the test subjects used should reflect the intended wearer group.

Table 1 also presents guidance on the type of test that could be included in performance standards to ensure adequate compliance with selected ergonomics factors.

Table 1 — Potential types of test for verifying ergonomic factors

Test type	Comment
Functional performance testing	Poor fit or other ergonomic inadequacies may impair the functional performance of the RPD. If any functional performance testing on human subjects is included, this may be sufficient for the verification.
Specific ergonomic testing	Where the impact of specific ergonomic factors is expected to have an adverse effect on activity or task performance, then testing for those factors should be specified.
Ergonomic practical performance test	Final verification of the suitability of the RPD should be established through appropriate practical performance test, e.g. as described in Annex A. These should reflect the overall impact of all ergonomics factors on wearability and acceptability.

5.3 Assessment of the anthropometric factors of RPD and their impact on the wearer

The following checklist should be used as a basis for RPD standards writers to assess and verify compliance with anthropometric principles.

— Range of wearers.

— Purpose for which the RPD is intended (e.g. activities and environment).

— Adequate fit requirements.

— Anthropometric measurements of wearers to ensure adequate fit across the range of wearers.

— Means of describing size categories to ensure correct selection of RPD for the wearers.

— In writing or revising a RPD standard, writers should consider the potential significance of each of these issues and ensure that they are adequately accommodated within the provisions of the standard. This may, for example, include defining the range of intended wearers and including a requirement for a representative sample from each of a number of designated size ranges in any testing (see for example ISO 15537[6]). The influence of fit on functional performance will be a critical factor here in establishing the relative importance of attending to anthropometric factors. However, functional performance should not be the sole criterion as a reluctance to wear poorly fitting RPD may negate any protective benefit.

5.4 Assessment of the biomechanical factors of RPD and their impact on the wearer

5.4.1 General

The information and data from the list in 4.7.1 should be used to determine whether biomechanical tests of the RPD are required.

5.4.2 Mass

The mass and mass distribution within the RPD should be evaluated with regard to the characteristics of the target population of wearers taking into account where it is worn on the body, the duration and/or frequency of wear and the activities likely to be undertaken while using the RPD. In determining whether or not some form of test or other requirement relating to the mass of the RPD is required.

5.4.3 Restriction of movement

The RPD standard writer should consider the likely extent of any possible restriction and whether or not this might hinder or prevent the wearer from carrying out general movements such as walking,

sitting, climbing stairs, etc. They should also consider whether or not this might hinder or prevent the wearer from carrying out such movements as are considered necessary to carry out specific activities appropriate for the intended use. If such general or specific impediment might reasonably be anticipated then an appropriate test should be devised and included in the standard.

5.4.4 Abrasion and compression of the skin and underlying structures

Negative effect due to abrasion or compression from closely fitting RPD might exist. Provision for assessment should be included in the standard. This may take the form of a practical performance test incorporating appropriate movements and postures.

5.4.5 Vibration

Where wearers of the RPD might be exposed to vibration from the RPD then provisions for assessment should be included in the standard.

5.5 Assessment of the thermal effects of RPD and their impact on the wearer

Performance standards writers should determine the possible impact of thermal effects of RPD on the wearer. If such an analysis shows that there are effects which could cause thermal discomfort or strain then the performance standards for that RPD should contain requirements for assessing its suitability.

A variety of approaches to the assessment of the thermal effect of the RPD are available for the performance standard writer to select from. These include tests on the materials, on complete RPD and on human subjects.

Where the relationship between material characteristics and the effects on the intended wearers is known then tests of material characteristics may be an appropriate method for inclusion in a performance standard.

With appropriate precautions, assessment of the complete RPD using human subjects provides a direct indication of its effects.

5.6 Assessment of the sensory factors of RPD and their impact on the wearer

5.6.1 General

This subclause presents guidance on the likely sensory factors of different forms of RPD and on possible test approaches to assess these.

5.6.2 Vision aspects of RPD

5.6.2.1 Field of vision

The range or field of vision from a static head position varies between individuals. The actual shape takes a complex multi-centred elliptical form. However, in the two major axes it extends 110° to left and right, 40° degree vertically upwards at the centre, and 70° downwards on the same axis. These measures represent the maximum field of vision that should be provided wherever feasible.

Specification of a minimum acceptable field of vision depends upon the intended use of the RPD and should be specified in the performance standards accordingly. It is essential that the effect on visual perception including peripheral vision is taken into consideration.

The effective field of vision allowed by an RPD can be measured in the laboratory for example as described in ISO 16900-11[8].

5.6.2.2 Visual acuity

Where items of RPD actually cover the eyes, two test criteria can be identified relating to visual acuity and to the accuracy of colour transmission. As with the field of vision, the criterion values to be applied will depend upon the intended application. At one extreme, complete transparency, lack of distortion and chromatic faithfulness may be required, particularly considering that any distortion of the visual field can have effects on balance, in extreme cases causing unwanted effects such as nausea. In other instances distortion of peripheral parts of the field of view may be regarded as acceptable.

Visual distortion can be determined according to ANSI Z 87.1[18] or ISO 16900-7[7]. Alternatively, standard ophthalmic tests could be specified. If considered appropriate, colour transmission can also be examined in practical performance test or in standardized objective or semi-objective tests.

5.6.2.3 Visual impairment during use

Visibility may become obscured or impaired during normal use. For example, visors may become misted with condensation of sweat, or scratched or abraded during use. Standards writers may wish to consider the extent to which these are likely. Some objective tests, such as those cited in EN 166[16], may be appropriate. Alternatively, it may be possible to adapt tests such as those outlined above to quantify such effects. For example, in the absence of an appropriate objective test, the visual field can be determined subjectively using the RPD, following an appropriate period of physical work within the practical performance testing.

5.6.3 Auditory aspects of RPD

5.6.3.1 Acoustical factors of RPD

RPD may change the sound at the ear; a means of assessing sounds should be made such that wanted sound is not distinctly reduced and unacceptable noise is not created by the RPD. Examples where this can occur include occlusive designs of devices such as assisted filtering devices with loose fitting respiratory interface (powered helmet respirators) where fan noise may have a masking effect. With some forms of RPD unwanted noise can create a hazard to hearing.

Specific test criteria are given in ISO 16900-14[21].

5.6.3.2 Assessment of impairment of speech or auditory warning signals

Wearing RPD can lead to a reduced recognition and/or transmission of specific sounds and/or their direction.

Where speech intelligibility and/or perception of warning signals are deemed to be an appropriate criterion, an assessment can be used for speech communication (ISO 9921[3]) or warning signal recognition (ISO 7731[1], EN 457[17]).

Performance standards writers should address hearing and speech by considering the information given in ISO/TS 16976-7[13].

5.6.4 Odour or taste aspects of RPD

The primary sense of taste is represented by one of only four basic tastes, i.e. sweet, sour, salt and bitter. The senses of taste and smell are, in a practical sense, largely inseparable. The pleasantness or unpleasantness of a smell or taste is essentially subjective although few would consider extremely foul smells to be attractive. Ideally, an item of RPD should have no distinguishable odour or taste at least none when worn normally. Where it has a distinguishable odour then subjective practical performance tests can be used to determine the acceptability or otherwise of the odour.

Test subjects should not be known to be sensitized to any odour, taste or suffer from olfactory fatigue.

5.6.5 Skin contact aspects of RPD

5.6.5.1 Irritation effects

Roughness, sharp edges, projections and other features of the RPD such as cold or hot surfaces (for more information see ISO/TS 16976-5[12]), which may cause unacceptable irritation, should be avoided. As well as direct sensory effects, irritation sensory exposure can disturb or distract wearers from concentrating on their tasks. Some forms of RPD have been found to create static electricity which results in discomfort or pain when wearing the RPD, particularly when taking it off or discharging the electricity in some other way.

Commonly known materials, such as Latex, to which large groups of wearers might have allergic reaction, should not be used in RPD design.

Skin irritation or reduced circulation of the blood caused by pressure are known to exist with some forms of RPD and can lead to considerable discomfort and consequent reluctance to use the RPD in question.

Appropriate test activities should be included in practical performance testing for evaluation of irritation effects.

5.6.5.2 Tactile effects

Impairment of tactile contact is likely only to be an issue with gloves when worn during use of a RPD or other forms of PPE covering the hands, as the extent of acquisition of tactile information through other pathways is very limited. As far as an acceptable level of impairment of tactile contact is concerned, this is clearly highly dependant on the balance between the protective and task requirements which may be in conflict. For example, manual control means which form part of a RPD should be designed for access and activation for wearers wearing gloves if appropriate to the application. Warning devices which rely on tactile sensation should be placed such that it is not affected by other PPE.

Appropriate test activities should be included in practical performance testing for evaluation of tactile effects.

Annex A
(informative)

Ergonomic assessment of RPD using panels of test subjects

A.1 General

The ergonomic factors of RPD affect the comfort, mobility and dexterity of users, the rate at which they develop fatigue, the efficiency with which they can work in the RPD, the interaction of the RPD with other PPE, and the effectiveness of the protection provided. However, it is not always possible to provide numerical requirements for physical measurements on the RPD for all these ergonomic factors. Assessments have to be made while people are wearing the RPD, and many of them will be subjective. Where a characteristic can reasonably be objectively assessed then such testing is preferable to the subjective appraisal of a practical performance testing.

How people wear RPD and how they are operated are influenced by the information for use supplied by the manufacturer. This information related to donning, use and doffing should be assessed.

This annex provides an example of how assessments might be specified to be made and how the acceptability or non-acceptability of the RPD may be determined. This annex is not intended to be used instead of specific ergonomic testing provided in performance standards.

All types of RPD should be subjected to practical performance test assessment according to their performance standard. The complexity of the RPD should guide the design of the assessments. In the clauses below, a comprehensive assessment is described. This should be altered where appropriate.

Fire fighter PPE assessment standard writers should refer to BS 8469[19].

Human testing of RPD is an essential part of the functional assessment of the effectiveness of the system and of its possible detrimental effects on the wearer.

A.2 Principle

An appropriate number of members of a panel of subjects, selected from the target wearer group shall don the RPD, carry out prescribed movements, and doff the RPD.

Observers watch the subjects and question them. The observers determine whether the RPD is acceptable or has such major flaws in its design or construction that it is unacceptable for the use intended, and therefore does not meet minimum requirements.

Any practical performance test based on ergonomic factors specified in a performance standard should include:

— description of the subjects, the task or movement;

— description of the conduct of tests to replicate elements of the movements the users would perform;

— details of the evaluation of the results of the tests and derivation of limit values.

A.3 Practical performance test

Test subjects representing the intended wearer group, i.e. medically fit and trained adults, should be selected. The number of test subjects is specified in ISO 17420-1[14] and ISO 17420-2[15].

The following essential test parameters should be considered, where applicable:

- the ease of donning the RPD with or without assistance as is appropriate for the type of RPD;
- the comprehensibility and accuracy of the user instructions for donning and adjusting the RPD;
- the adequacy of the range of adjustments available;
- the ease of doffing the RPD with or without assistance as is appropriate for the type of RPD;
- the compatibility of the RPD with other items of PPE as identified by the RPD manufacturer;
- any assessment of movements and tasks according to the relevant practical performance test, such as:
  - standing, sitting, walking, running, climbing stairs, crawling, jumping,
  - talking,
  - picking up a small object from the floor,
  - picking up a heavier object and carrying it some distance,
  - performing hand, arm and torso movements while standing or seated as at a machine,
  - holding specific equipment, and possibly simulating the operation of it,
  - reaching out for objects in all directions, including two-handed reach above the head,
  - getting in and out, and sitting in or driving a vehicle,
  - taking a rest and starting the 'activity' again,
  - getting through restricted spaces,
  - getting down on the ground and getting up again,
  - movements characteristic of users of the particular RPD,
  - climbing a ladder,
  - swimming and submersion,
  - carrying out any of the tasks with other RPD/PPE normally worn with the items under evaluation;
- any physiological measurements to be made on subjects;
- any self-assessment performed by test subjects, e.g. in accordance with ISO 10551[4][subjective evaluation method, rating of perceived exertion scale (Borg-Scale)];
- the limit values for physiological variables of subjects during the practical performance test in accordance with ISO 9886[2] and ISO 12894[5];
- the criteria by which task performance are to be assessed;
- record of the relevant environmental conditions, such as air temperature any other environmental variable of importance; and
- documentation of the results.

A.4 Duration of tests

Any test should be in accordance with the intended duration of use of RPD. Such practical performance tests should be of sufficient duration to provide indications before any circulatory or neural effects, for example, become apparent.

A.5 Test for thermal effect

A.5.1 General

Tests in RPD performance standards should be designed to ensure that the defined limits for general and local thermal comfort and for thermal strain are not exceeded when the anticipated activity is carried out for normal durations.

Tests are conducted to evaluate the combined effects of RPD and work clothing at predicted highest and lowest temperatures.

Any such testing can be undertaken only by specialist staff from laboratories suitably qualified for the purpose. Human tests always require approval by an appropriate ethics committee. Human testing requires medical supervision when appropriate.

Guidance on supervision can be found in 4.3.3.

A.5.2 Task

The physical activity of the subjects during the tests should match as closely as possible those of the intended use.

If accurate simulation is not possible, the body movements of the wearers and the level of metabolic energy expenditure should be as close as possible to that of the test subject.

A.5.3 Subjects

As with other testing, subjects should be drawn from the wearer group. If it is not possible to use a representative sample from the wearer group then the sample used should match as closely as possible that of the wearer group for the individual characteristics of most importance:

— age,

— height,

— body mass,

— gender,

— facial characteristics,

— body fat content,

— physical fitness,

— skill at the task being simulated.

A.5.4 Subject safety

Throughout the testing process the health and welfare of the subjects should be of paramount importance. All subjects should be volunteers who have given informed consent to participate in the practical performance test.

Bibliography

[1] ISO 7731, *Ergonomics — Danger signals for public and work areas — Auditory danger signals*

[2] ISO 9886, *Ergonomics — Evaluation of thermal strain by physiological measurements*

[3] ISO 9921, *Ergonomics — Assessment of speech communication*

[4] ISO 10551, *Ergonomics of the thermal environment — Assessment of the influence of the thermal environment using subjective judgement scales*

[5] ISO 12894, *Ergonomics of the thermal environment — Medical supervision of individuals exposed to extreme hot or cold environments*

[6] ISO 15537, *Principles for selecting and using test persons for testing anthropometric aspects of industrial products and designs*

[7] ISO 16900-7, *Respiratory protective devices — Methods of test and test equipment — Part 7: Practical performance test method*[1)]

[8] ISO 16900-11, *Respiratory protective devices — Methods of test and test equipment — Part 11: Determination of field of vision*

[9] ISO/TS 16976-1, *Respiratory protective devices — Human factors — Part 1: Metabolic rates and respiratory flow rates*

[10] ISO/TS 16976-2, *Respiratory protective devices — Human factors — Part 2: Anthropometrics*

[11] ISO/TS 16976-3, *Respiratory protective devices — Human factors — Part 3: Physiological responses and limitations of oxygen and limitations of carbon dioxide in the breathing environment*

[12] ISO/TS 16976-5, *Respiratory protective devices — Human factors — Part 5: Thermal effects*

[13] ISO/TS 16976-7, *Respiratory protective devices — Human factors — Part 7: Hearing and speech*

[14] ISO 17420-1, *Respiratory protective devices — Performance requirements — Part 1: Supplied breathable gas devices*[2)]

[15] ISO 17420-2, *Respiratory protective devices — Performance requirements — Part 2: Filtering devices*[3)]

[16] EN 166, *Personal eye protection — Specifications*

[17] EN 457, *Safety of machinery — Auditory danger signals — General requirements, design and testing*

[18] ANSI Z 87.1, *American National Standard for Occupational and Educational Personal Eye and Face Protection Devices*

[19] BS 8469, *Personal protective equipment for firefighters — Assessment of ergonomic performance and compatibility — Requirements and test methods*

[20] World Medical Association Declaration of Helsinki. "Ethical Principles for Medical Research Involving Human Subjects" http://www.wma.net/en/30publications/10policies/b3/

[21] 16900-14, Respiratory protective devices — Methods of test and test equipment — Part 14: Measurement of sound level[4)]

1) Under preparation.

2) Under preparation.

3) Under preparation.

4) Under preparation.

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